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December 11, 2003

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APPLICATION NUMBER: ***60/420,724***
FILING DATE: ***October 23, 2002***
RELATED PCT APPLICATION NUMBER: *PCT/US03/33240*

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Docket No: ESNZ 2 00028 P (+)

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I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents Washington, D.C. 20231.

By: Hilary M. McNULTY

PROVISIONAL APPLICATION UNDER 37 CFR 1.53(c)
TRANSMITTAL LETTER

ASSISTANT COMMISSIONER OF PATENTS
WASHINGTON, D.C. 20231

Transmitted herewith for filing is the Provisional Patent application of:

First Inventor's name: Edward T. SCHNEIDER
Residence address: 216 East Island
Eastlake, OH 44094
Citizenship: US

Entitled: "SMART" DECUBITI MAT

Enclosed are:

3 Pages of **SPECIFICATION**
1 Pages of **DRAWINGS**

x **VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS**

___ Independent Inventor
x Small Business
___ Non-profit Organization

___ **OTHER** (Specify) _____

x A **CHECK** in the amount of $ 80.00 for the Provisional application Filing Fee is enclosed.

X The Commissioner is hereby authorized to charge any additional fees which may be required at any time during the prosecution of this application without specific authorization, or to credit any overpayment, to Deposit Account No. 06-0308. A duplicate copy of this sheet is enclosed.

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government:

X No

___ Yes, the name of the U.S. Government agency and the Government contract numbers are:

_____

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TCAM PRODUCT OPPORTUNITY
"SMART" DECUBITI MAT

PRODUCT JUSTIFICATION

THE PRESSURE SORE (DECUBITUS ULCER) PROBLEM AND COSTS

Pressure sores are a high profile problem for hospitals and nursing homes. Occurrence in nursing homes is estimated at 17 to 27% of the patients. Hospital estimates indicate that over 11% of their patients have this condition at any given time, and the particular researcher commented that hospitals probably under-report this factor. According to one literature source, nursing homes and hospitals *in the U.S.* are estimated to treat over 1 million patients per year at an estimated total cost of $55 billion dollars annually, or $52,000 per patient. Another source, reporting on the *worldwide* incidence, indicates that at any given time, there are 7 million patients suffering from Decubiti Ulcers globally. Other less detailed sources cite lower costs for annual *U.S.* national health care of Decubiti Ulcers at $1.35 billion.

Pressure sores are caused by high pressure points on the body over extended periods that close off capillaries in the skin, causing tissue death. They most frequently occur in patients on hospital beds, on surgical tables, and wheelchair seats. Surgical tables are most severe in that the patient is under deep anesthesia and will not move to protect himself from pressure points. It is reported that a pressure sore can occur in 5 minutes on a surgical table due to this factor, but in beds and wheelchairs it's occurrence is more correlated with extended time periods. They occur most often on the buttocks, back of head, heels and shoulders where bony prominences in the body come in contact with the support surface. Pressure sores are more prevalent in patients, typically elderly, with compromised circulation with low blood pressure.

We have been given a verbal estimate by a marketing person with Decubiti products that annual Decubiti product sales total over $1 billion. Individual products are targeted to the above bed, table and wheelchair sites, and are produced in different sizes to accommodate. Traditional products include lambs wool, low-tech foam, high-tech foam ('Temperfoam'), gel filled mattresses, air mattresses, oscillating air mattresses, patient tilting mattresses, and pressure sensing polymer mats which generate a visual read-out of pressure points. We have recently become aware of three different R&D efforts to develop next generation mats including high tech computerized load sensing and redistribution solutions. The problem is receiving much government attention, with a large number of research grants being let to pursue solutions.

COMPETITIVE DESIGN APPROACHES

The key elements of the solution to pressure sores is to avoid high pressure areas, to vary the points of body support over time, and to avoid pooled sweat in contact with the body. This leads to mats that conform to the body and allow air circulation such as lamb's wool and pump pressurized air mattresses with air vents under the patient. Air mattresses, foam mats and gel filled mats do distribute the load more evenly than firmer supports to reduce pressure points, but the amount of grant activity and new R&D in this market is an indication better solutions are desired.

There is one product that is a thin plastic mat with pressure sensors embedded on it to measure and give a visual readout of the high pressure areas on a computer monitor. This product is not capable of making any adjustments to reduce the high load areas, and presumably is a teaching aid or used to guide nurses as to where to place pillows, foams or mats.

We have met with two R&D groups who are pursuing a high tech computerized solution by combining distributed pressure sensors with air mattresses to sense high pressure areas and then manipulate air valves to distribute the load. The air mattresses have a cellular structure (like 'blister' packs) and individual valves and lines would be run to each cell to allow computer adjustment.

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PRODUCT COST CONSIDERATIONS

The high prevalence of pressure sores quoted above indicates that a large number of prophylactic devices are needed to effectively avoid the possibility of this trauma. Presumably, patients could be screened for high risk factors, and a limited number of mats could be issued to those most in need, but the reliability of this type of screening in avoiding problems is typically well below 100% effectiveness. With the current high litigation environment in the health care markets, any patient who gets screened out from receiving a Decubiti mat, yet develops pressure sores, has a very good basis for a lawsuit. Hence, the desired usage pattern would probably approach 100% if product costs vs. hospital budgets allowed. I would estimate the typical hospital budget would probably not support high priced products in any great numbers.

With 1 million patients annually suffering from pressure sores, if the screening process issued two mats for every incident, that would indicate a usage pattern of 2 million applications per year in the U.S., and 14 million worldwide. At a 100% mat/patient issue rate, the usage pattern would be 9 times that for U.S. hospitals and 4 times for U.S. nursing homes. Averaging those numbers at 6.5 times the number of annual U.S. cases (1 million) indicates something like 6.5 million uses per year.

The considerations above indicate that the most desirable products would require reasonable pricing that enables the wider usage pattern. This wider usage would offer more protection to hospitals from lawsuits. The simplest product, a sheepskin (yes, a real sheepskin) sells for $85 to $345 (king-size) and is washable (reusable). The costs of higher tech existing products are currently being investigated.

New high tech mats design approaches have a serious cost challenge. A full body mat (30" by 72") that used cells that were 2" x 2" would require 540 individual cells. I am using the 2" x 2" cell size estimate to make a point, but I personally believe they would need to be smaller to effectively distribute the load, increasing the number of cells. If we assume the computer operated design discussed at the end of the last section, each of the 540 cells would require an electronic pressure sensor, a control valve, electric wiring, plastic tubing, and an individual, dedicated air tube feeding it. The computer control would require 540 electrical valve outputs and 540 pressure sensor inputs. Costs could be reduced by using flexible printed circuits on the mat backing to poll the pressure sensors, but the valve package most probably would have to be remote from the mat, requiring 540 lines to the mat. If we assume $20 per cell to implement this hardware intensive package, at 540 cells, the mat production cost would be $10,800! Additionally, an air compressor support package is needed, which would contain the computer board and valves.

Perhaps they can do better on cost per cell than my estimate, but the proliferation of hardware would also generate high maintenance needs to keep the mats operational. The combination of low cost hardware, flexible structures and large numbers of cells would typically lead to high maintenance.

It is my opinion that this high-tech approach is too hardware intensive for meeting the 'reasonable cost' and reliable service approach that is needed to become a 'staple' product in these markets.

THE TCAM "SMART" DECUBITI MAT CONCEPT.

In reviewing the product needs, we have developed the following customer driven product specification;

1. The cost of the device must be low enough to allow large scale purchase by hospitals (the initial assumption is under $1000, but additional market research may indicate under $500).
2. The device must provide 'active' or intelligent load re-distribution.
3. The device must also provide a slow oscillating or massaging action.
4. The device must vent air under the patient to eliminate pooled sweat.
5. The actual mat portion of the device (excluding the remote durable air supply) must be semi-disposable due to frequent damage by poor handling, needlesticks, and patient shear (sliding on the mat). Note that hospitals really like one-time use and disposables use items since it gives them a direct line item to add to the patient's bill.
6. The mat must be disinfectable and preferably sterilizable (higher level of assurance).

Additionally marketing considerations provide the following desirable features in such a product;

7. A strong aftermarket sales potential of replacements for disposable or semi-disposable components of the product is desirable. The marketing razor – razor blade concept is to give customers the razor and sell them replacement blades forever. In this product, the initial sale of the two components of a durable air supply package and a semi-disposable mat places the customer in the economic position that when a mat becomes damaged but the air supply is functional, buying a replacement mat (from us) is cheaper than buying a complete new product (possibly from a competitor). This can generate a market "lock-in" situation where our product becomes the standard. Additionally, we would design-in some key patentable feature, such as a custom air connection fitting, which we can use to block aftermarket sales of 'copycat' replacements by the competition.

8. A technically simple product to minimize the costs of providing product service support, but still allowing product service contracts to be sold to the customer. Simple maintenance needs would give us wider lattitude in choosing multiple sales and distribution channels, and include distributors with weaker service capabilities.

9. A very low production cost for the semi-disposable mat with a high mark-up to a market costs which meets the 'reasonable' cost factors needed by the customer.

Our concept is to ***not*** use a modern computer software and hardware intensive approach due to costs and complexity, but to use thermally expanding polymers in a simple and inexpensive mechanism in each cell of the mat to regulate load. We would sense body heat to control airflow to individual cells, alternately deflating or inflating cells depending on body contact. A TCAM polymer sensor in contact with the body at 98.6 degrees F. would receive more heat from the body if the contact force were higher, and less heat if the contact force is lower. Sensors not in contact with the body at all would experience the 70 degrees F. of room air. The polymer sensors would inflate as they heat up toward 98.6 F. and deflate as they cool towards 70 F. ambient. The opposite action is needed from the air pressure inflated cells of the mat – they must deflate under high pressure points (higher temp.), and inflate under low pressure points (low temp.). The expansion of the polymer would impede a flow channel in the mat delivering pressurized air to the cell (creating a simple valve in the mat), and an atmospheric vent in the cell would then deflate the individual cell. A cell with contracted polymer would allow full pressurized airflow to the cell, overcoming the venting action and inflating the cell. This load redistribution action would meet Specification 2.

The mat construction is envisioned to utilize the well developed vinyl air mattress construction methods which allows very complex mat to be made very inexpensively, meeting semi-disposable product cost goals in Specifications 1, 5, 7, 9.

Careful design of the heat transfer factors from the body to the polymer sensor would allow development of a constantly oscillating cell undergoing periodic inflation and deflation cycles. This action is very common in thermal systems such as a heating system that constantly alternates between too hot or too cold, and can be deliberately designed in. This would meet the 'massage' requirement in Specification 3.

The vents designed into the mat would exhaust 70 F. air under the patient, carrying away sweat accumulation, meeting Specification 4.

Investigation of vinyl or other stronger, heat sealable plastic material mat can be made in the design to insure the materials resistance to common disinfectants and sterilants. It is known that a wide variety of plastics can be disinfected, and a more limited variety can be sterilized by existing techniques. This would meet Specification 6.

The durable Air Supply and Mat would utilize a patented, custom tube connection to the mat to protect against competitive sales of aftermarket mats, meeting Specification 7.

The semi-disposable nature of the mat would eliminate service of that product in favor of replacement. The durable Air Supply would be a very simple air compressor and pressure regulator using common, state of the art pneumatic components with simple service requirements. It is not envisioned to need microchips or valves in the supply. This would meet Specifications 1, 8.

"SMART" DECUBITI MAT CONCEPT